



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to medium-chain triglycerides and reduction in body weight (ID 643, 677, 1614) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
[10.2903/j.efsa.2011.2240](https://doi.org/10.2903/j.efsa.2011.2240)

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

[Link back to DTU Orbit](#)

Citation (APA):
EFSA Publication (2011). *EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to medium-chain triglycerides and reduction in body weight (ID 643, 677, 1614) pursuant to Article 13(1) of Regulation (EC) No 1924/2006*. European Food Safety Authority. the EFSA Journal No. 2240 <https://doi.org/10.2903/j.efsa.2011.2240>

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to medium-chain triglycerides and reduction in body weight (ID 643, 677, 1614) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to medium-chain triglycerides and reduction in body weight. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is medium-chain triglycerides. In the context of the references provided, the Panel assumes that the food constituent which is the subject of the health claims is medium-chain fatty acids, which should replace long-chain fatty acids in triglycerides in order to obtain the claimed effect. The Panel considers that the food constituent, medium-chain fatty acids, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effect.

The claimed effect is “weight management”. The target population is assumed to be overweight individuals in the general population who wish to reduce their body weight. The Panel considers that reduction in body weight is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the results from the human intervention studies provided are inconsistent with respect to the effects of medium-chain triglycerides on body weight loss, and that the evidence in support of a mechanism by which medium-chain triglycerides could exert the claimed effect is weak and not convincing.

¹ On request from the European Commission, Question No EFSA-Q-2008-1430, EFSA-Q-2008-1464, EFSA-Q-2008-2350, adopted on 08 April 2011.

² Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjödin and Inge Tetens.

The Panel concludes that a cause and effect relationship has not been established between the consumption of medium-chain triglycerides and reduction in body weight.

KEY WORDS

Medium-chain triglycerides, long-chain triglycerides, replacement, body weight, health claims.

TABLE OF CONTENTS

Summary	1
Table of contents	3
Background as provided by the European Commission	4
Terms of reference as provided by the European Commission	4
EFSA Disclaimer.....	4
Information as provided in the consolidated list	5
Assessment	5
1. Characterisation of the food/constituent	5
2. Relevance of the claimed effect to human health (ID 643, 677, 1614)	5
3. Scientific substantiation of the claimed effect (ID 643, 677, 1614)	5
Conclusions	9
Documentation provided to EFSA	9
References	9
Appendices	11
Glossary and Abbreviations	17

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is medium-chain triglycerides (MCTs).

In the context of the references provided, the Panel assumes that the food constituent which is the subject of the health claims is medium-chain fatty acids (MCFAs), which should replace long-chain fatty acids (LCFAs) in triglycerides in order to obtain the claimed effect. In the context of the references provided, the Panel assumes that MCFAs (6-10 carbon atoms), mostly caprylic (C:8) and capric (C:10) acids in a ratio of approximately 2-3 to 1 in the form of triglycerides, should replace LCFAs (>12 carbon atoms) in the form of triglycerides (LCTs) in order to obtain the claimed effect.

The Panel considers that the food constituent, MCTs, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health (ID 643, 677, 1614)

The claimed effect is “weight management”. The Panel assumes that the target population is overweight individuals in the general population who wish to reduce their body weight.

In the context of the proposed wordings and the references provided, the Panel assumes that the claimed effect refers to reduction in body weight.

Weight loss can be interpreted as the achievement of a normal body weight in previously overweight subjects. In this context, weight loss in overweight subjects without achieving a normal body weight is considered to be a beneficial physiological effect.

The Panel considers that reduction in body weight is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect (ID 643, 677, 1614)

The majority of the references provided for the scientific substantiation of the claim reported on the effects of food constituents other than MCTs and/or on health outcomes (e.g. acute or short-term

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

⁵ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

effects on appetite ratings, energy intake, fat oxidation and/or regulatory hormone concentrations, blood lipids, energy expenditure, and body composition) other than body weight. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

A total of ten publications reporting on nine human intervention studies which addressed the effects of MCT *vs.* LCT consumption on body weight were provided (Beermann et al., 2003; Han et al., 2007; Kasai et al., 2003; Krotkiewski, 2001; Nosaka et al., 2003; St-Onge and Jones, 2003; St-Onge et al., 2003a; St-Onge et al., 2003b; Tsuji et al., 2001; Yost and Eckel, 1989). Two publications reported on the same study (St-Onge and Jones, 2003; St-Onge et al., 2003b).

Two of the studies were designed to assess the metabolic effects of replacing LCTs by MCTs, and had a randomised, parallel design, a duration of two and four weeks, and included five and eight subjects per intervention group, respectively (Beermann et al., 2003; Yost and Eckel, 1989). The Panel notes the small sample size of these studies, which may have been inappropriate to assess changes in body weight, and considers that no conclusions can be drawn for the scientific substantiation of the claim.

In a parallel, randomised, double-blind intervention study (Tsuji et al., 2001), the effects on body weight of 10 g/day MCTs were compared to the effects of 10g/day LCTs (blended rapeseed oil and soybean oil) in bread consumed daily at breakfast for 12 weeks in healthy men and women. A total of 100 subjects were randomised but only 78 completed the study and entered data analysis. Dietary counselling was provided to all subjects at the beginning of the study. Compliance with the study diet aiming to maintain energy balance was self-reported. Body weight was measured at weeks 0, 4, 8 and 12. Data from subjects with BMI ≥ 23 kg/m² or < 23 kg/m² were presented separately. Data analyses for the entire study population were not provided. It is unclear whether this sub-group analysis was planned at recruitment [(BMI ≥ 23 kg/m²: n=26 (MCTs), n=30 (LCTs); BMI < 23 kg/m²: n=15 (MCTs), n=7 (LCTs)]. The differences in raw data were examined by two-way ANOVA. The significance of differences between the groups for the same period was assessed by unpaired Student's *t*-test (two-tailed). It is unclear from the publication whether initial body weight was included as a covariate in the two-way ANOVA, or whether the MCT and LCT groups were comparable at baseline regarding body weight (mean \pm SEM=75.7 \pm 1.9 kg *vs.* 72.8 \pm 1.1 kg). The Panel notes the substantial limitations of the study, and considers that no conclusions can be drawn from it for the scientific substantiation of the claim.

In a randomised, cross-over, controlled feeding intervention (St-Onge et al., 2003a), the effects on body weight of diets rich in either MCTs or LCTs (as olive oil) for periods of four weeks each were assessed in 17 healthy obese women. Diets contained 40 % of energy as fat, 15 % as protein and 45 % as carbohydrates, were designed for body weight maintenance, and all meals were provided to the subjects for the duration of the study under strictly controlled conditions. Of the total amount of fat, 75 % was derived from either beef tallow (LCTs) or a blend of saturated and unsaturated vegetable oils (MCTs). In the MCT diet, 50 % of the total fat was provided by MCT oil, rich in octanoate and decanoate (49 and 50 % of total fatty acids respectively), 10 % by olive oil and 5 % each by butter, coconut oil and flaxseed oil. An unesterified plant sterol/stanol mixture at a level of 22 mg/kg body weight/day was added to the MCT diet to maintain normal cholesterol concentrations. Wash-out periods were of 4-8 weeks to ensure that all women were assessed in the same phase of the menstrual cycle. No significant differences in weight loss between the two study phases were observed (-0.87 \pm 0.16 kg *vs.* -0.84 \pm 0.22 kg during MCT and LCT consumption, respectively). The Panel notes that this study did not show a significant effect of MCTs on body weight at doses of about 55 g/day for four weeks in the context of a diet aiming at energy balance.

In a randomised, cross-over, controlled feeding trial (St-Onge and Jones, 2003; St-Onge et al., 2003b), the effects on body weight of diets rich in either MCTs or LCTs (as olive oil) for periods of four weeks each were assessed in 24 healthy overweight men. Diets contained 40 % of energy as fat, 15 %

as protein and 45 % as carbohydrate, and were designed for body weight maintenance. The diets were identical except for the quality of the fat. The MCT-containing diet contained an oil composed of 64.7 % MCT oil, 12.6 % olive oil, 6.8 % each of canola and flaxseed oil, and 5.8 % coconut oil as the main source of fat (75 % of total fat). The control diet (LCTs) contained 75 % of total fat as olive oil. The MCT oil also contained 3.4 % unesterified stanol/sterol mixture. No significant differences in weight loss between the two study phases were observed (-1.03 ± 0.25 kg *vs.* -0.62 ± 0.29 kg during MCT and LCT consumption, respectively). The Panel notes that this study did not show a significant effect of MCTs on body weight at doses of >55 g/day for four weeks in the context of a diet aiming at energy balance.

In a parallel, randomised, double-blind intervention trial (Krotkiewski, 2001), the effects on body weight of MCT *vs.* LCT supplementation during a very low calorie diet (VLCD) were assessed. Three groups of matched obese women (BMI >30 kg/m²) received an isoenergetic (578.5 kcal) VLCD enriched with MCTs (8.0 g/100g providing 8 kcal/g, $n=22$) or LCTs (9.9 g/100 g providing 9 kcal/g, $n=22$), or a low-fat (3.0 g/100 g, $n=22$) and high-carbohydrate regimen. The diets were administered over four weeks. Body weight significantly decreased in the MCT group compared to the LCT and low-fat group at weeks 1 and 2 of the study, but no significant differences in body weight changes were observed between groups at the end of the study (weeks 3 and 4). The Panel notes that this short-term study did not show a significant effect of MCTs on body weight.

In a parallel, randomised, double-blind intervention trial (Han et al., 2007), the effects on body weight of a test oil with MCTs (extracted from coconut oil, 100 % MCTs with a caprylic acid:capric acid ratio of 2:1) as compared to corn oil (control LCTs), at doses of 18 g/day administered as part of the daily diet were assessed in 40 free-living subjects with type-2 diabetes mellitus living in an urban area of China. Subjects were on treatment with oral antidiabetic medication (sulfonylureas, biguanides or α -glucosidase inhibitors), which were maintained constant during the study. All subjects completed the study and reported being fully compliant with the intervention. Body weight was assessed on days 0, 45 and 90 of the study. Differences between groups at the same time point were assessed using ANOVA, with baseline data as covariate, and Tukey *post-hoc* tests. Body weight in the MCT group was significantly lower than in the LCT group at days 45 and 90 of the study ($p<0.05$; $p=0.012$ for the time-group interaction). Body weight decreased in the MCT group by approximately 1.5 kg, and increased by approximately 0.28 kg in the LCT group. The authors reported that no significant effect of medication use on body weight was detected in either group. However, the Panel notes that this effect was not formally tested in the study, and that the information provided is limited to the type of medication received by each study subject. A significant reduction in energy and fat intake assessed using a three-day weighed food record (first and last week of the study) was also observed in the MCT group compared to the LCT group. The Panel notes that a body weight difference of about -1.7 kg in 12 weeks in favour of MCTs was observed in this study at doses of 18 g/day without imposed energy restriction.

In a parallel, randomised, double-blind intervention trial (Nosaka et al., 2003), the effects on body weight of margarines (14 g/day) containing 5 g of MCTs or an equal amount of LCTs (blended rapeseed oil and soybean oil) consumed with bread at breakfast for 12 weeks were studied. Of the 73 subjects (18 female) recruited and randomised, two dropped out for reasons unrelated to the study, and seven subjects were excluded from data analysis owing to protocol violation. Data analyses were conducted in the population of completers ($n=64$, $n=33$ in the MCT group) only. Dietary counselling was provided to all subjects at the beginning of the study. Compliance with the study diet aiming to maintain energy balance was self-reported. Body weight was measured at weeks 0, 4, 8 and 12. A significant reduction in body weight ($p<0.05$) was observed at week 12 in the MCT group as compared to the LCT group (mean \pm SD= -4.2 ± 2.8 kg *vs.* -2.9 ± 2.0 kg) The Panel notes that a weight difference of about -1.3 kg in 12 weeks in favour of MCTs was observed at doses of 5 g/day in the context of an isoenergetic diet, and that differences in body weight between the MCT and LCT groups were only significant at week 12 of the study.

In a parallel, randomised, double-blind intervention trial (Kasai et al., 2003), the effects on body weight of a test bread made with 14 g of cooking oil (obtained by transesterification of 14 % MCTs and 85 % rapeseed oil) with structured medium and long-chain triglycerides (MLCTs) containing 1.7 g MCFAs were compared to the effects of a bread made with LCTs (blended rapeseed oil and soybean oil). Bread or control breads were consumed daily at breakfast for 12 weeks. Of the 93 subjects recruited and randomised, 10 could not consume the specified meal, and one subject dropped out. Data analyses were conducted in the population of completers (n=82, 7 female, n=40 in the MCT group, 4 female) only. Dietary counselling was provided to all subjects at the beginning of the study. Compliance with the study diet aiming to maintain energy balance was self-reported. Body weight was measured at weeks 0, 4, 8 and 12. A significant reduction in body weight ($p<0.05$) was observed at weeks 4, 8 and 12 in the MCT group as compared to the LCT group (mean \pm SEM=-2.4 \pm 0.2 kg, -3.5 \pm 0.3 kg, -4.5 \pm 0.4 kg in the MCT group at weeks 4, 8 and 12 as compared to -1.7 \pm 0.2 kg; -2.5 \pm 0.3 kg; -3.3 \pm 0.4 kg in the LCT group). The Panel notes that a weight difference of about -1.2 kg in 12 weeks in favour of MCTs was observed at doses of 1.7 g/day in the context of an isoenergetic diet, and that differences in body weight between the MCT and LCT groups were already significant at 4 weeks (body weight loss difference of about -0.7 kg in favour of MCTs).

The Panel notes that three human intervention studies of 12 week duration observed a significant effect of MCTs on body weight loss at MCT doses of 1.7-18 g/day in the context of diets aiming at energy balance (Han et al., 2007; Kasai et al., 2003; Nosaka et al., 2003), and that the body weight difference between the MCT and LCT groups (range 1.3-1.7 kg) was rather uniform and apparently independent of the MCT doses used. The Panel also notes that one of the studies already observed a significant effect of MCTs on body weight at four weeks (Kasai et al., 2003) using 1.7 g/day MCTs, whereas no effect of MCTs was reported at the same time point at higher doses (>50 g/day) in the context of isoenergetic (St-Onge and Jones, 2003; St-Onge et al., 2003a; St-Onge et al., 2003b) or energy-restricted (Krotkiewski, 2001) diets in more strictly controlled studies.

A number of possible mechanisms by which MCTs could exert the claimed effect have been proposed, and the evidence for these has been reviewed by Kovacs and Mela (2006). MCTs are readily hydrolysed by lipases in the gastro-intestinal tract, and unlike LCTs are directly absorbed into the portal circulation and transported to the liver for oxidation. The intra-mitochondrial transport of MCTs does not require carnitine palmitoyltransferase, which possibly accelerates oxidation of MCTs and possibly limits storage within tissues. However, the exact mechanism by which MCTs could have an effect on energy balance is unclear. In animals, there is some evidence that consumption of MCTs may increase satiety, decrease energy intake, and increase energy expenditure, resulting in lower body weight and smaller fat depots compared to isocaloric LCT consumption. However, results from human studies are conflicting. High intakes of MCTs lead to reduced energy intakes in some studies at doses of 18-60 g/day, but no effects on appetite, request for food or changes in any satiety-related hormone have been observed at these intake levels. Similarly, increased energy expenditure following consumption of MCTs at high doses (15-50 g/day) has been observed in the short-term (7 days), whereas results for longer periods of time are inconsistent. No effects of MCTs at lower doses of intake (about 10 g/day) have been observed on any of these variables. The Panel considers that the evidence provided for a mechanism by which MCTs could exert the claimed effect is weak and not convincing.

In weighing the evidence, the Panel took into account that the results from the human intervention studies provided are inconsistent with respect to the effects of MCTs on body weight loss, and that the evidence in support of a mechanism by which MCTs could exert the claimed effect is weak and not convincing.

The Panel concludes that a cause and effect relationship has not been established between the consumption of MCTs and reduction in body weight.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent that is the subject of the health claims is medium-chain triglycerides (MCTs). It is assumed that the food constituent which is the subject of the health claims is medium-chain fatty acids (MCFAs), which should replace long-chain fatty acids (LCFAs) in triglycerides in order to obtain the claimed effect. The food constituent, MCTs, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effect.
- The claimed effect is “weight management”. The target population is assumed to be overweight individuals in the general population who wish to reduce their body weight. Reduction in body weight is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of MCTs and reduction in body weight.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1430, EFSA-Q-2008-1464, EFSA-Q-2008-2350). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

REFERENCES

- Beermann C, Jelinek J, Reinecker T, Hauenschild A, Boehm G and Klor HU, 2003. Short term effects of dietary medium-chain fatty acids and n-3 long-chain polyunsaturated fatty acids on the fat metabolism of healthy volunteers. *Lipids in Health and Disease*, 2, 10.
- Han JR, Deng B, Sun J, Chen CG, Corkey BE, Kirkland JL, Ma J and Guo W, 2007. Effects of dietary medium-chain triglyceride on weight loss and insulin sensitivity in a group of moderately overweight free-living type 2 diabetic Chinese subjects. *Metabolism: Clinical and Experimental*, 56, 985-991.
- Kasai M, Nosaka N, Maki H, Negishi S, Aoyama T, Nakamura M, Suzuki Y, Tsuji H, Uto H, Okazaki M and Kondo K, 2003. Effect of dietary medium- and long-chain triacylglycerols (MLCT) on accumulation of body fat in healthy humans. *Asia Pacific Journal of Clinical Nutrition*, 12, 151-160.
- Kovacs EM and Mela DJ, 2006. Metabolically active functional food ingredients for weight control. *Obesity Reviews*, 7, 59-78.
- Krotkiewski M, 2001. Value of VLCD supplementation with medium chain triglycerides. *International Journal of Obesity and Related Metabolic Disorders*, 25, 1393-1400.
- Nosaka N, Maki H, Suzuki Y, Haruna H, Ohara A, Kasai M, Tsuji H, Aoyama T, Okazaki M, Igarashi O and Kondo K, 2003. Effects of margarine containing medium-chain triacylglycerols on body fat reduction in humans. *Journal of Atherosclerosis and Thrombosis*, 10, 290-298.
- St-Onge MP and Jones PJ, 2003. Greater rise in fat oxidation with medium-chain triglyceride consumption relative to long-chain triglyceride is associated with lower initial body weight and greater loss of subcutaneous adipose tissue. *International Journal of Obesity and Related Metabolic Disorders*, 27, 1565-1571.

- St-Onge MP, Bourque C, Jones PJ, Ross R and Parsons WE, 2003a. Medium- versus long-chain triglycerides for 27 days increases fat oxidation and energy expenditure without resulting in changes in body composition in overweight women. *International Journal of Obesity and Related Metabolic Disorders*, 27, 95-102.
- St-Onge MP, Ross R, Parsons WD and Jones PJ, 2003b. Medium-chain triglycerides increase energy expenditure and decrease adiposity in overweight men. *Obesity Research*, 11, 395-402.
- Tsuji H, Kasai M, Takeuchi H, Nakamura M, Okazaki M and Kondo K, 2001. Dietary medium-chain triacylglycerols suppress accumulation of body fat in a double-blind, controlled trial in healthy men and women. *Journal of Nutrition*, 131, 2853-2859.
- Yost TJ and Eckel RH, 1989. Hypocaloric feeding in obese women: metabolic effects of medium-chain triglyceride substitution. *American Journal of Clinical Nutrition*, 49, 326-330.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁶ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

Foods are commonly involved in many different functions⁸ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁶ OJ L12, 18/01/2007

⁷ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁸ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to medium-chain triglycerides, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
643	medium chain triglycerides (MCT)	weight management	- helps to manage body weight, - helps to reduce body fat particularly in overweight persons, - helps to limit body fat accumulation, - helps to increase energy expenditure.
	Conditions of use <ul style="list-style-type: none"> - 5g/day - from 2g to 10g/day 		
ID	Food or Food constituent	Health Relationship	Proposed wording
677	Medium Chain Triglycerides; MCT;	Weight management	Consumption of Medium Chain Triglycerides (MCT) inside the normal suggested fat consumption contributes to keep the healthy balanced body weight and helps to avoid fat deposition, with special regards to the abdominal fat.;MCT helps to increase energy expenditure in comparison to the long chain fatty acids by increasing the metabolic rate.
	Conditions of use <ul style="list-style-type: none"> - 30-40 g/day short term use; 5 g/day;long term use 		
ID	Food or Food constituent	Health Relationship	Proposed wording
1614	Medium Chain Triglycerides (MCT)	Weight management	Helps to increase satiety after a meal /helps to increase energy expenditure by increasing the metabolic rate /helps with weight loss by increasing metabolic rate /tends to reduce body weight and fat in overweight persons
	Conditions of use <ul style="list-style-type: none"> - 5g/day - 30-40 g/day short term use; 5 g/day;long term use - kurzfristig 30-40 g/Tag, langfristig 10 g/Tag - from 2g to 10g/day - 30-40 g/day short term use. 10 g/d long term use 		

GLOSSARY AND ABBREVIATIONS

BMI	Body mass index
LCFA	Long-chain fatty acid
LCPUFA	Long-chain polyunsaturated fatty acid
LCSFA	Long-chain saturated fatty acid
LCT	Long-chain triglyceride
MCT	Medium-chain triglyceride
MLCT	Medium and long-chain triglycerides
VLCD	Very low calorie diet